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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,565	11/13/2003	Harvey A. Fishman	S02-296/US	8264

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LUMEN INTELLECTUAL PROPERTY SERVICES, INC.
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EXAMINER

FORD, ALLISON M

ART UNIT PAPER NUMBER

1651

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/713,565

Applicant(s)

FISHMAN ET AL.

Examiner

Allison M. Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39,43,48,52 and 57-60 is/are rejected.
- 7) ☒ Claim(s) 40-42,49-51 and 53-56 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Response to Amendments

Applicant's amendments filed 01 August 2005, replacing claims 24-38 with new claims 39-61, have been entered. Claims 24-38 have been cancelled. The terminal disclaimer filed 01 July 2005 has obviated the double patenting rejections.

Priority

Acknowledgement is made of applicant's claim for priority as a CIP of US application 10/184,210 filed 06/27/2002, which further claims priority to provisional application 60/301,934 filed 06/29/2001.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47 and 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's claim 47 is indefinite because it requires a well to be connected to the reservoir via the aperture; however parent claim 44 requires a channel to connect the reservoir to the aperture. Therefore, it appears the connection between the well and the reservoir involves both the aperture and the channel.

Applicant's claim 57 is dependent on cancelled claim 1; it appears claim 57 is intended to be dependent on new claim 39, examination has been conducted as such.

Claim Objections

Claims 40-42, 49-51, and 53-56 are objected to as being dependent on a rejected base claim, but would be allowable if rewritten in dependent form including all limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 39, 43 & 57-59 are rejected under 35 U.S.C. 102(e) as being anticipated by Iezzi et al (US Patent 6,668,190), which is fully supported by provisional application 60/212,214.

Applicant's claim 39 is directed to a device for modulating neuronal activity, said device comprising (a) a housing having a surface biocompatible with at least a portion of a neuronal cell; (b) an aperture in said surface; (c) a reservoir connected to said aperture; and (d) a flow regulator in operable relationship with fluid in said reservoir for moving the fluid to the aperture. Claim 43 requires the fluid to comprise a bioactive agent. Claim 57 is directed to a method of stimulating a neuronal cell, comprising inserting the device of claim 39 in proximity to a neuronal site, wherein the fluid in the device comprises a bioactive agent. Claim 58 requires the neuronal site to be a retinal site. Claim 59 requires the bioactive agent to be a neurotransmitter.

Iezzi et al teach a drug delivery device for stimulating neurological tissue, in particular for the stimulation of neuronal tissue in the retina, and a method for using the device to stimulate the neurological tissue.

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The device of Iezzi et al comprises a chip comprising two major surfaces and one minor surface (which applicant calls a housing). The major surface of the chip is intended to be in contact with neurological tissue containing neurological cells, thus the major surface is biocompatible with at least a portion of a neuronal cell. The device further comprises a reservoir that is connected to the chip by microfluidic channels, the microfluidic channels end in conduits that open onto the major surface of the chip (at what applicant calls apertures on the surface). The device further comprises a pump (which applicant calls a flow regulator) which functions to pass fluid in the reservoirs through the microfluidic channels to the major surface of the chip (See col. 4, ln 10-col. 8, ln 34, especially col. 5, ln 42-col. 6, ln 32 & Fig. 3-5). The reservoirs hold neuro-activ pro-drugs (which applicant calls bioactive agents); the neuro-activ pro-drugs can include neurotransmitters (see col. 7, ln 11-13).

Iezzi et al further teach a method of using the device described above involving attaching the chip to the retina and delivering the bioactive solution to the chip, thereby stimulating the neuronal cells (See col. 8, ln 35-col. 9, ln 5). Iezzi et al teach that the bioactive drugs can comprise neurotransmitters (see col. 7, ln 11-13). Therefore the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 48, 52, and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iezzi et al (US Patent 6,668,190), which is fully supported by provisional application 60/212,214, in view of Mallapragada et al (US Patent 6,676,675).

Applicant's claim 48 is directed to a device for modulating neuronal activity, said device comprising (a) a housing of flexible material having a surface biocompatible with at least a portion of a neuronal cell; (b) an aperture in said surface; (c) a reservoir connected to said aperture; and (d) a flow regulator in operable relationship with fluid in said reservoir for moving the fluid to the aperture. Claim 52 requires the fluid to comprise a bioactive agent. Claim 60 is directed to a method of stimulating a neuronal cell, comprising inserting the device of claim 48 in proximity of a neuronal site, wherein the fluid in the device comprises a bioactive agent.

Iezzi et al teach a drug delivery device for stimulating neurological tissue, in particular for the stimulation of neuronal tissue in the retina, and a method for using the device to stimulate the neurological tissue. The device comprises a housing comprised of two biocompatible major surfaces and a minor surface; a reservoir that contains bioactive agents for stimulating cells at the neuronal site; microfluidic channels that run from the reservoir to conduit openings (which applicant calls apertures) on the major surface of the chip; and a pump that functions to deliver the fluid in the reservoir through the microfluidic channels to the openings on the major surface of the chip (which applicant calls a flow regulator). Iezzi et al also teach a method of using the device to stimulate neuronal cells in the retina. See teachings above.

Iezzi et al is silent on the material of the chip surfaces. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use flexible, biocompatible materials for the chip surfaces. One of ordinary skill in the art would have been motivated to use flexible materials for the chip surfaces because the chip is intended to be implanted in the retinal region of the eye; therefore in order to accommodate the curvature of each individual's eye, and well as movement and flexing of the eye muscles, the material of the implanted portion of the device needs to be flexible. One would have had a reasonable expectation of success because flexible chip-forming materials, such as silicon, poly (D, L-lactide), glycolic acids, glycolid trimethylene carbonate, polyester, polyglycolic acids, collagen, polylactic

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acid, poly(organo)phosphazine, polyorthoester, glycosoaminoglycan, L-lactide, e-caprolactone, polyurethane, polyimides, or polystyrene, are well known in the art (See, e.g. Mallapragada et al col. 2, ln 40-65). Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

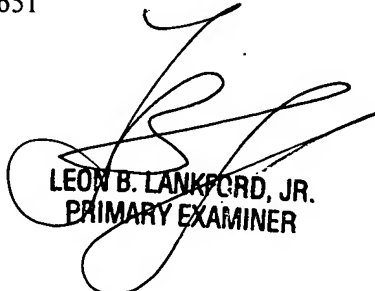
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford
Examiner
Art Unit 1651


LEON B. LANKFORD, JR.
PRIMARY EXAMINER